



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Direct Impact Corona Ionization Mass Spectrometry

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the Food and Drug Administration, an agency within the Department of Health and Human Services, through the National Institutes of Health Office of Technology Transfer is contemplating the grant of an exclusive worldwide license to practice the inventions embodied in HHS Ref. No. E-258-2011/0, "Direct Impact Corona Ionization (DICI) Mass Spectrometry;" U.S. Patent 8,704,169, to Vivione Biosciences, Inc., a corporation incorporated under the laws of the State of Arkansas, having a principle place of business at 515 W. Matthews Ave., Jonesboro, AR. 72401.

The United States of America is the assignee of the patent rights pertaining to this invention.

The exclusivity period of the contemplated license may be granted for no more than seven (7) years, may be territorially limited to the United States and may be limited

to a field of use directed to direct impact corona ionization mass spectrometry pattern recognition devices and systems for detection of small molecules and microbiological agents.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq, CLP, Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; E-mail: shmilovm@mail.nih.gov. A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under the publication rules of either the U.S. Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

E-258-2011/0 (U.S. Patent 8,704,169) – The invention relates to the uses of an AccuTOF DART (time-of-flight mass spectrometer coupled to direct analysis in real time) mass spectrometer for qualitatively analyzing samples (originally designed for microbes) based on the serendipitous discovery that glowing direct impact corona

ionization greatly enhances sensitivity of identification. This direct impact corona ionization occurred while repositioning the stainless steel pin too close to the grid of the ion source gun. Examination revealed that not only did the peak intensity increase by 490 fold but the spectral information was well beyond anything seen before with only the normal ionization mode on the same instrument. Initially, pyrolysis was considered necessary for vaporizing low volatility components of microbiological analytes, a prerequisite for ionizing and introducing samples into the mass spectrometer. However, pyrolysis introduced particles from burned electrical wiring insulation because of the high current necessary. As an alternative, the inventors replaced the pyrolysis device with a power generator used for direct corona ionizing microbiological analytes in a controlled fashion. Furthermore, a small custom-made glass cylinder with two juxtaposing holes on each side was set up within the sample introduction chamber to exclude oxygen thus preventing oxidation of microbiological analytes. Additionally, the insulation provided by this cylinder kept out ambient moisture thus ensuring proton transfer from water molecules would not contribute to irreproducible ionization of the analyte.

The prospective exclusive license will be royalty-bearing and comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, the National Institutes of Health Office of Technology Transfer receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections

submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 17, 2014

Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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